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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,376	09/29/2005	Hideyuki Yamato	Q90275	3147

23373 7590 03/03/2009

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EXAMINER	
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ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
03/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,376	YAMATO, HIDEYUKI	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 9 and 11-12 are pending. Applicant cancelled claims 1-8, 10, and 13-20. Applicant amended claims 9 and 11. Applicant is advised that a different Examiner is examining the instant application. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 11-12a are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating low-turnover bone disease by administering to a subject in need thereof a spherical activated carbon in an effective

amount, does not reasonably provide enablement for a method of preventing low-turnover bone disease by administering to a subject in need thereof a spherical activated carbon in an effective amount. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

An analysis based upon the Wands factors is set forth below.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993),. See also *Amgen Inc. v. Chugai Pharm. Co*., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman (230 USPQ 546, 547 (Bd Pat App Int 1986)). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Breadth of Claims

Applicant's claims are not overly broad.

Nature of the invention/State of the Prior Art

Applicant's claimed invention is drawn to a method of treating or preventing low-turnover bone disease by administering to a subject in need thereof a spherical activated carbon in an effective amount. Low bone turnover is a consequence of chronic kidney failure and associated low parathyroid hormone (PTH) levels ((i) Davies et al. *Journal of the American Society of Nephrology*, **2005**, *16*, pp 917-28, especially page 917, right column; (ii) Felsenfeld et al. *Kidney International*, **1993**, *43*, pp 771-789; (iii) Merck Online Home Edition, "Chronic Kidney Failure", www.merck.com/mmhe/print/sec11/ch143/ch143c.html –accessed February 22, 2009; and (iv) Coen, G. "Adynamic bone disease: an update an overview", *J. Nephrol*. **2005 Mar-Apr**, *18(2)*, abstract only). Clinically, low bone-turnover is called adynamic bone disease. Treatments for chronic kidney failure include dialysis, kidney transplantation, and the administration of spherical activated carbon (Sonobe et al. U.S. Patent No. 6,830,753: especially column 7, lines 33-49). The prior art does not recognize that the administration of spherical activated carbon results in the prevention of low bone-turnover disease. It is also noted that a disease or disorder cannot be prevented once it has occurred. Applicant's animal model data supports the notion that the administration of spherical activated carbon is suitable for the treatment of low bone-turnover disease. Applicant's data does not demonstrate the prevention of low bone-turnover disease, because the animal models already were suffering from low bone turnover disease prior to administration of the spherical activated carbon. Thus, there is no scientific basis to support the conclusion that the administration of activated carbon will prevent the development of low bone-turnover disease. The term prevention is interpreted herein in the absolute sense to mean that a subject receiving an administered dose of spherical activated

carbon will never develop adynamic bone disease. It is noted that "prevention" is not defined in Applicant's specification.

Level of One of Ordinary Skill & Predictability/Unpredictability in the Art

The level of a person of ordinary skill in the art is high, with ordinary artisans having advanced medical and/or scientific degrees (e.g. M.D., Ph.D., Pharm. D. or combinations thereof). There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427, F. 2d 833, 166, USPQ 18 (CCPA 1970).

Guidance/Working Examples

Applicant provides animal model data (i.e. a murine model) demonstrating the treatment of low bone turnover by the administration of spherical activated carbon. Applicant's data does not demonstrate the prevention of low bone turnover by the administration of spherical activated carbon. Applicant does not identify any dosages or dosing frequencies as being adequate to prevent adynamic bone disease. Applicant merely concludes that the animal model data is evidence that adynamic bone disease can be prevented by practicing Applicant's claimed method. Thus, an ordinary skilled would be required to undertake burdensome experimentation, such as clinical trials, to determine what dosages and dosing regimens, if any, would prevent a subject from ever developing low bone-turnover disease (i.e. adynamic bone disease) upon administration of spherical activated carbon. In conclusion, the specification, while being enabling for a method of treating low-turnover bone disease by administering to a subject in need thereof a spherical activated carbon in an effective amount, does not reasonably provide

enablement for a method of preventing low-turnover bone disease by administering to a subject in need thereof a spherical activated carbon in an effective amount.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonobe et al. (US 2003/0118581) ("Sonobe") (already of record) as evidenced by the Merck Online Home Edition article, entitled, "Chronic Kidney Failure", www.merck.com/mmhe/print/sec11/ch143/ch143c.html –accessed February 22, 2009 ("Merck").

Applicant Claims

Applicant's claims have been described above.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Sonobe teaches a method of treating a renal disease (e.g. a kidney disease) comprising administering to a subject in need thereof a porous spherical carbonaceous substance (i.e. activated carbon). The renal disease may be a primary renal disease selected from the group including **chronic renal failure and/or a secondary disease caused by the primary disease** [0050].

Merck teaches that renal osteodystrophy (i.e. adynamic bone disease) is a secondary disease resulting from chronic renal failure.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Sonobe does not explicitly state or identify secondary diseases caused by the primary disease as including adynamic bone disease. This deficiency is cured by Merck.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious that treatment of chronic renal failure would necessarily result in the treatment of renal osteodystrophy (i.e. adynamic bone disease), because adynamic bone disease is a result of chronic bone disease. Thus, treatment of chronic renal failure necessarily results in treatment of adynamic bone disease. An ordinary skilled artisan

would have been motivated to treat adynamic bone disease by the administration of spherical activated carbon as taught by Sonobe and would have had a reasonable expectation of success, because etiologically, adynamic bone disease is a consequence of chronic renal failure and the treatment of its cause (i.e. chronic renal failure) would reasonably be expected to result in the successful treatment of adynamic bone disease. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9 and 11-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-7 of U.S. Patent No. 6,830,753 (USPN '753) as evidenced by the Merck Online Home Edition, "Chronic Kidney Failure", www.merck.com/mmhe/print/sec11/ch143/ch143c.html –accessed February 22, 2009 ("Merck"). The claims of the instant application have been described *supra*. Claim 5 of USPN '753 claims a method of treating a renal disease (i.e. a kidney disease) comprising administering to a subject in need thereof a porous spherical carbonaceous substance (i.e. activated carbon). Dependent claim 6 of USPN '753 specifies that the renal disease is a primary renal disease selected from a group including chronic renal failure and/or a secondary disease caused by the primary disease. The claims of USPN '753 do not explicitly state or identify secondary diseases caused by the primary disease. Merck teaches that renal osteodystrophy (i.e. adynamic bone disease) is a secondary disease resulting from chronic renal failure. Thus, it would have been prima facie obvious that treatment of chronic renal failure would necessarily result in the treatment of renal osteodystrophy. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 9 and 11-12 *prima facie* obvious over claims 5-7 of USPN '753.

Conclusion

Claims 9 and 11-12 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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